REMARKS

Claims 2-6, 11, 13-20, 25 and 28-86 are currently pending, with claims 15, 16, 18-20, 25, 36 and 37 being withdrawn from consideration. Claims 2, 3, 35, 38, 39, 40, 45, 46 and 47 have been amended to remove the term "preventing." Basis for this amendment is found on page 7, lines 23-28 of the specification. Claims 11 and 14 have been amended to include the limitation that the 24-hydroxyvitamin D and the 24-hydroxy*pre*vitamin D have no hydroxyl groups at the C1 position. Basis for this amendment is found on page 9, lines 10-19 and page 13 and 14 of the specification. Applicants submit that no new matter has been added.

Claims 2, 3, 38, 39, 40, 45, 46 and 47 stand rejected under 35 USC § 112 first paragraph as not being enabled for the "prevention" of the medical disorders set forth therein. Claims 2-6, 11, 13, 14, 17 and 28-86 stand rejected under the judicially created doctrine of obviousness type double patenting over U.S. Patent No. 6,150,346. Claims 2-6, 11, 13, 14, 17, 20 and 28-86 stand rejected under the judicially created doctrine of obviousness type double patenting over U.S. Patent No. 6,242,434. Applicants respectfully traverse these rejections for at least the following reasons.

Rejections under 35 USC § 112, first paragraph

The Examiner has rejected claims 2, 3, 38, 39, 40, 45, 46 and 47 under 35 USC § 112, first paragraph as not being enabled for the "prevention" of the medical disorders set forth therein. The Examiner, however, indicated that these claims were enabled for "treating" the disorders. Applicants have amended claims 2, 3, 35, 38, 39, 40, 45, 46 and 47 to remove the term "preventing" so that the claims are solely related to "treating." In light of these amendments, Applicants respectfully request that the rejections be withdrawn.

Obviousness type double patenting over U.S. Patent No. 6,150,346

The Examiner has rejected claims 2-6, 11, 13, 14, 17 and 28-86 stand rejected under the judicially created doctrine of obviousness type double patenting over U.S. Patent No. 6,150,346 (hereinafter the "'346 Patent"). The Examiner has argued that claims of the invention which are drawn to "24-hydroxyvitamin D" and "24-hydroxy*pre*vitamin D" are

generic and therefore overlap with the claims of the 1α-hydroxy*pre*vitamin claims of the '346 patent. Applicants respectfully submit that the claims, as amended herein, are not obvious over the claims of the '346 Patent.

As indicated in our previous response, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103, with the exception that only the claims of the cited patent are used to determine whether the claims of the pending application are taught or suggested. To establish obviousness-type double patenting, the inventions defined in the claims of the '346 Patent claims must first be identified. The inventions defined in the claims of the '346 Patent are:

> "[a]n improved and stabilized previtamin D oral formulation, said formulation comprising a therapeutically effective amount of substantially pure, solvent-free crystalline 1α-hydroxyprevitamin D ...." (claim 1 of the '346 Patent)

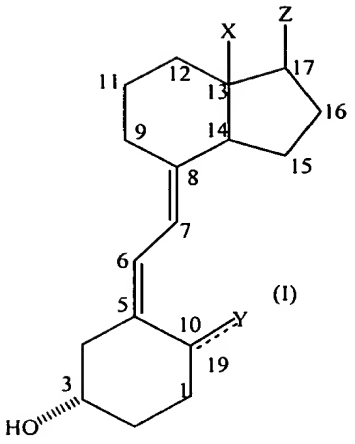
and

> "[a] method for treating or preventing osteoporosis in a human being, comprising administering orally to said human being in need thereof an effective amount of the previtamin D oral formulation of claim 1." (claim 6 of the '346 Patent).

The claims of the '346 Patent define only "previtamin D formulation[s] comprising 1α-hydroxyprevitamin D" and a "method of treating or preventing osteoporosis" by "administering ...the previtamin D oral formulation." All previtamin D compounds defined in the claims are hydroxylated in the 1α-position. Claim 2 of the '346 Patent defines that the previtamin D compounds may also be dihydroxylated, e.g., in the 1α-position and in the 24-position, such as "1α,24-dihydroxyprevitamin D_2" (see, claim 2 of the '346 Patent).

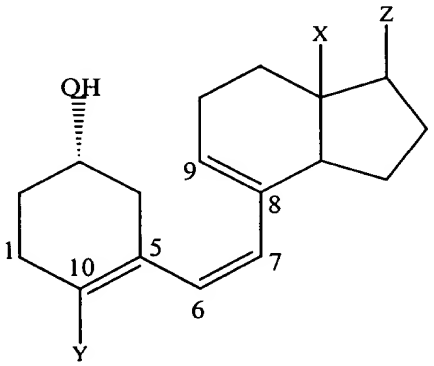
In contrast, the invention defined by the instant claims is a method of use of 24-hydroxylated vitamin D and 24-hydroxylated previtamin D, i.e., neither the previtamin nor the vitamin form are hydroxylated in the 1α-position.

In the present application, claim 4 and claim 2, upon which claims 35 and 38-44 depend, are limited to a 24-hydroxyvitamin D of formula (I). For clarification, the 24-hydroxyvitamin D of formula (I) is shown below with the appropriate carbon numeration. The compound of formula (I) contains no hydroxyl group at the C1 position.



(I)

Claim 3 of the present application, upon which claims 28-34 and 45-51 depend, and claim 13, upon which claims 60-68 depend, are limited to a 24-hydroxy*pre*vitamin D of formula (III). For clarification, the 24-hydroxy*pre*vitamin D of formula (III) is shown below with the appropriate carbon numeration. The compound of formula (III) contains no hydroxyl group at the C1 position.



(III)

Claim 11 of the present application, upon which claims 52-59 depend, and claim 14, upon which claims 5, 6, and 69-86 depend are limited to "a 24-hydroxyvitamin D wherein there is no hydroxyl group at the C1 position or a 24-hydroxy*pre*vitamin D wherein there is no hydroxyl group at the C1 position."

As indicated above, all of the pending claims of the application are limited to a structure where there is no hydroxylation in the C1 position. As the claims of the '346 patent neither teach nor suggest such a limitation, the claims of the present application cannot be found to be obvious over the claims of the '346 patent.

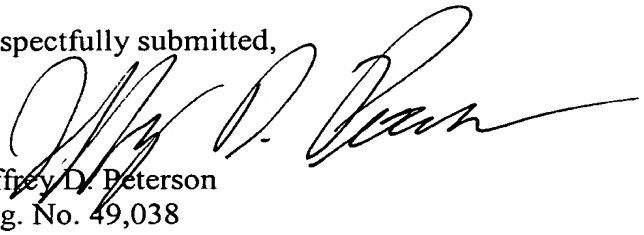
Obviousness type double patenting over U.S. Patent No 6,242,434

The Examiner has rejected claims 2-6, 11, 13, 14, 17, 20 and 28-86 under the judicially created doctrine of obviousness type double patenting over U.S. Patent No. 6,242,434. 37 CFR § 1.130 provides that a judicially created double patenting rejection can be obviated by the filing of a terminal disclaimer. Applicants herewith have provided a terminal disclaimer in accordance with 37 CFR § 1.321(c) to commonly owned U.S. Patent No. 6,242,434. Applicants therefore respectfully submit that this rejection be withdrawn.

SUMMARY

Based on the foregoing, Applicants respectfully submit that the present application is in condition for allowance, and a favorable action thereon is respectfully requested. Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



Jeffrey D. Peterson
Reg. No. 49,038

Docket No.: 17620/9316
Michael Best & Friedrich LLP
One South Pinckney Street
P. O. Box 1806
Madison, WI 53701-1806
(608) 257-3501
Q:\client\017620\9316\B0330291.1